Express Mail Label No.	Dated:

Docket No.: 03042/000G956-US0

(PATENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

James D. Marks

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Application No.: 09/556,945

Art Unit: 3626

Filed: April 21, 2000

Examiner: Robert W. Morgan

For: SYSTEM AND METHOD FOR

RECRUITMENT OF CANDIDATES FOR CLINICAL TRIALS WHILE MAINTAINING

**SECURITY** 

## SECOND DECLARATION OF BONNIE GOLDMAN

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

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- I, Bonnie Goldman, hereby declare and state as follows:
- 1. I am a citizen of the United States and am more than twenty-one years of age.
- 2. From August 1995 to November 18, 1999, I was employed by Body Health Resources Corporation ("BHRC") as a consultant with the title Content Manager. Since November 19, 1999, I have been an employee of BHRC. As a consultant and an employee, I have worked on behalf of and under the direct supervision and control of James D. Marks, Founder and Chief Executive Officer.

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Declaration Under 37 C.F.R. § 1.131

3. This Declaration supplements a Declaration earlier made by me on August 19, 2004, and which, upon information and belief, was transmitted to the United States Patent & Trademark Office on August 19, 2004.

- 4. The following paragraphs describe work that was completed by me, along with individuals working on my behalf and under my supervision and control. The work was completed in the United States.
- 5. I directed the design and implementation of web site pages on www.thebody.com presenting a Health Survey Questionnaire and accompanying information about the purpose and use of the Questionnaire (including information about the protection of privacy of the respondents, the confidentiality of the responsive data, the ability of respondents subsequently to remove themselves from BHRC's list, and a participation agreement). The purpose of the Health Survey Questionnaire was to solicit health and contact information from members of the public, provided with gratuitous access to the web site, for possible participation in one or more upcoming clinical trials. The Health Survey Questionnaire was first installed on a server for posting on www.thebody.com and made accessible to members of the public through access to www.thebody.com via the Internet between May 21, 1999 and, at the latest, May 24, 1999, the first date for which www.thebody.com received responses to the Questionnaire. (For the responses, see Exhibit C of my Declaration of August 19, 2004). Responses were encrypted and transmitted securely to the server on which the Health Survey Questionnaire was installed.
- 6. As of May 24, 1999 at the latest, the Health Survey Questionnaire accessible to members of the public included at least the following web site pages posted at www.thebody.com:

  The page headlined, "Volunteer for Research," at <a href="http://www.thebody.com/surveys/health\_survey.html">http://www.thebody.com/surveys/health\_survey.html</a> (substantially in the form attached as Exhibit G of the Declaration of Christopher Andrews), the page headlined, "Volunteer for Research! Participation Agreement," at <a href="http://www.thebody.com/surveys/health\_survey1.html">http://www.thebody.com/surveys/health\_survey1.html</a> (substantially in the form attached as Exhibit H of the Declaration of Christopher Andrews), the page headlined, "Health Survey," at <a href="http://www.thebody.com/surveys/health\_survey2a.ihtml">http://www.thebody.com/surveys/health\_survey2a.ihtml</a> (substantially in the

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form beginning on page 8 of Exhibit L, attached to the Second Declaration by James D. Marks dated October 31, 2007), and the page headlined, "Removing Your Name from *The Body's* List of Volunteers for Research," at <a href="http://www.thebody.com/surveys/health\_remove.ihtml">http://www.thebody.com/surveys/health\_remove.ihtml</a>. Upon information and belief, the Removal Page was substantially in the form later captured on September 12, 1999 at archive.org (an entity independent of BHRC), which may be viewed currently at <a href="http://web.archive.org/web/19990912024121/http://www.thebody.com/surveys/health\_remove.ihtml">http://web.archive.org/web/19990912024121/http://www.thebody.com/surveys/health\_remove.ihtml</a> a current hardcopy of which is attached as Exhibit P. This page provided the fillable form further described in paragraph 11.

- 7. In order to avoid releasing confidential information during the removal process, removal requests, like registrations, were encrypted and transmitted securely to the server on which the Health Survey Questionnaire was installed. This avoided a potential security hole, because if people with HIV revealed their identities or medical information in ordinary email requesting removal, such email could be intercepted and read by unintended parties. The page headlined "Health Survey", which is attached as Exhibit L to the Second Declaration by James D. Marks dated October 31, 2007, required registrants to provide their birthdates for at least the reason that BHRC could use birthdate to verify identity in case BHRC later received a request for removal that purported to be from the registrant. Accordingly the Removal Page as well was designed to collect birthdate, as further described in paragraph 11.
- 8. The pages posted at TheBody.com headlined, "Volunteer for Research," and "Volunteer for Research! Participation Agreement," in addition to being substantially in the form of Exhibits G and H in the Declaration of Christopher Andrews, were moreover as of May 24, 1999 substantially in the form later captured at archive.org (showing .jpg graphics) on October 2, 1999 and on July 12, 2000 respectively, located respectively at the following URLs: <a href="http://web.archive.org/web/19991002035408/http://www.thebody.com/surveys/health\_survey.html">http://web.archive.org/web/19991002035408/http://www.thebody.com/surveys/health\_survey1.html</a> and are attached respectively in current hardcopy form as Exhibits Q and R. The headline changed on the Participation Agreement page between May 24, 1999 and July 12, 2000, from "Volunteer for Research! Participation Agreement," to "Applying for Clinical Studies and Research/Participation

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Agreement," but the substance of the page remained the same, and specifically it always contained the link to the Removal Page further described in paragraph 10.

- 9. I also directed the design and implementation of a secure database for BHRC in which the data entered in response to the Health Survey Questionnaire and to the Removal Page was transmitted, stored and accessed by Dahlia Elsayed, an employee of BHRC at the relevant time. The secure database resulting from the responses to the Questionnaire contained personal and medical information from multiple members of the public.
- 10. Prior to May 24, 1999, upon information and belief, I and/or the individuals working on my behalf and under my supervision and control ("we") tested the web site pages which provided links to the Removal Page. Specifically, we confirmed that functioning links to the Removal Page were coded into the following text: into "Please remove my name as a volunteer" on the web site page <a href="http://www.thebody.com/surveys/health survey.html">http://www.thebody.com/surveys/health survey.html</a> and into the underlined portion of, "This release shall be effective for a perpetual duration, but <a href="you may subsequently request that The Body">you may subsequently request that The Body</a> no longer provide information to clinical researchers" on the web site page <a href="http://www.thebody.com/surveys/health survey1.html">http://www.thebody.com/surveys/health survey1.html</a>.
- 11. Prior to May 24, 1999, upon information and belief, we further confirmed that a fillable form provided on the Removal page for requesting, once registered, withdrawal from possible participation in upcoming clinical trials was operable to receive name and identifying information (a "birthdate") of a registered individual, and confirmed that the Removal Page was further operable to transmit this information in encrypted form to the server on which the Health Survey Questionnaire was located by operation of a "submit" button on the Removal Page.
- 12. Prior to May 24, 1999, upon information and belief, I provided instructions to Dahlia Elsayed, an individual working on my behalf and under my supervision and control, to download the encrypted responses to the Health Survey Questionnaire together with encrypted withdrawal requests, to decrypt them, to store them in an electronic database at our office, to print hard copies of the downloaded data, and to store the electronic and hard copy data in a secure fireproof file cabinet located at the office of BHRC in strict accordance with privacy and

confidentiality policies for the responses to the Questionnaire. A summary of these instructions is provided in my Declaration of August 19, 2004. Upon information and belief, I further instructed Dahlia Elsayed to fully delete the stored responses for whom withdrawal requests had been received.

13. I further declare that all statements made herein are of my own knowledge and are true, and that all statements made on information and belief are believed to be true. I further declare that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States code, and that such willful false statements may jeopardize the validity of the instant application or of any patent issued thereupon.

Respectfully submitted,

Bonnie Goldman

Dated: Ortober 3/, 200 7

Attachments:

Exhibit P: Copy of "Removing Your Name from The Body's List of Volunteers for

Research" Page

Exhibit Q: Copy of "Volunteer for Research" Page

Exhibit R: Copy of "Applying for Clinical Studies and Research/Participation Agreement"

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